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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,034	09/22/2003	James D. Ralph	SPINE 3.0-441 CONT CONT	1511
51640	7590	06/28/2010	EXAMINER	
SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			NELSON, CHRISTINE L	
			ART UNIT	PAPER NUMBER
			3775	
			MAIL DATE	DELIVERY MODE
			06/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,034	Applicant(s) RALPH ET AL.	
	Examiner CHRISTINE L. NELSON	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10,13,14,16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-10,13,14,16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>May 21, 2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

This action is in response to the amendment submitted on December 21, 2009. Claims 1-4, 6-10, 13, 14, 16, and 18-22 are pending in the application.

Allowable Subject Matter

The indicated allowability of claims 1-4, 6-10, 13, 14, 16, and 18-22 is withdrawn in view of the new rejection below.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “relative angle designation marks” and the “axially medial groove” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

Art Unit: 3775

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-10, 13, 14, 16, and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of a relative angle designation mark that *extends from the upper surface to the lower surface* is not found in the specification. In paragraph [0040] of the specification, "at least two relative angle designation marks" are disclosed, but the limitation of extending from the upper surface to the lower surface is not disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3775

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6-10, 13, 14, 16 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "axially medial groove" is used in the above listed claims, but does not appear in the specification. The term "annular groove" is used throughout the specification, but does not appear in the claims. It is the examiner's interpretation that these terms have been used interchangeably. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-10, 13,14, 16, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US Patent 6,425,920) in view of Gross et al (US Patent 5,306,308).

Regarding Claims 1 - 3, Hamada discloses (Figures 58-60) an intervertebral spacer (701) that is porous ([30], lines 4-11, noting that harvested allograft bone is porous) with a beveled edge (sloping outward as seen in Figure 60), a spacer body with a central bore (707) passing through the upper (703) and lower (705) surfaces where both of the surfaces are substantially flat, and the upper and lower surfaces

Art Unit: 3775

diametrically tapered (as seen in Figure 60). Hamada fails to disclose at least one relative angle designation mark extending from the upper surface to the lower surface and including two relative angle designation marks on at least one of the upper and lower surfaces. Gross teaches at least one relative angle designation mark (Figure 4d, 12) extending from the upper surface to the lower surface and including two relative angle designation marks (formed by the edges of the recess) on at least one of the upper and lower surfaces. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Hamada with the teaching of the recess of Gross, to avoid blocking nerve tracks by the implant.

Regarding Claims 4, 6-8, 16, 18, and 19, Hamada does not disclose a tapered axially medial groove. Gross et al teaches (Column 2, Lines 41-45) that a tapered axially medial groove (7') simplifies the surgical procedure by allowing the implant to be held and inserted by surgical forceps. Additionally, Gross has radially outwardly extending division lines, which would function as relative angle designation marks. Though not extending from the upper to the lower surface, these are evenly spaced and would provide the surgeon with a view of relative angle. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to combine the tapered medial groove and also the relative angle designation marks of Gross with the device of Hamada to allow surgical forceps to grip the implant and assist with placement by having relative angle marks, thereby facilitating the surgical procedure.

Regarding Claims 9, 10, 13, 14, and 20-22, Hamada does not disclose an upper radial flange disposed between the upper surface and the axially medial groove and a

Art Unit: 3775

lower radial flange disposed between the lower surface and the axially medial groove, where the at least one relative angle designation mark extends through at least one of the upper and lower radial flanges. Gross teaches an upper radial flange (Figure 4d – not labeled, but formed by the upper portion of the axially medial groove) disposed between the upper surface and the axially medial groove and a lower radial flange (Figure 4d – not labeled, but formed by the lower portion of the axially medial groove) disposed between the lower surface and the axially medial groove, where the at least one relative angle designation mark extends through at least one of the upper and lower radial flanges (Figure 4d). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the flanges (that occur as part of the axially medial groove) of Gross with the invention of Hamada as described above.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-10, 13, 14, 16, and 18-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE L. NELSON whose telephone number is

Art Unit: 3775

(571)270-5368. The examiner can normally be reached on Monday through Friday 7:30 to 5:00 - first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTINE L. NELSON/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775